Shelf Life Extension Program (SLEP)

Federal, State, and Local Public Health Preparedness Meeting: Legal and Regulatory Perspectives

Brad Leissa, MD
Co-Chair, FDA SLEP Rapid Response Team

Office of Counter-Terrorism and Emergency Coordination (OCTEC)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration
U.S. Department of Health and Human Services

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SLEP Background

- Established in 1986 under an inter-agency agreement (IAG) between DoD and FDA
- Congressional directive to address US Air Force drug stockpiles

SLEP Roles - DoD

- **Through the Defense Medical Standardization Board (DMSB), DoD performs programmatic / administrative functions:**
  - Identifies to FDA products/lots that need to be tested
  - Updates the SLEP expiration date database
  - Informs FDA of products eligible for testing
  - Computes financial benefits and cost
  - Orders labels for re-labeling; Bills participants

SLEP Roles - FDA

- **Performs testing and evaluation of drugs:**
  - Determines appropriate tests and methods
  - Tests product samples
  - Analyzes results for determining expiration extension
  - Performs research to address SLEP issues

SLEP Participants

- **U.S. Federal agencies that sign a Memorandum of Agreement (MOA) with DoD**
- DoD participants
  - US Army
  - US Air Force
  - US Navy
  - US Marines
- Strategic National Stockpile (SNS) – since 2004
- Dept. of Veterans Affairs (VA) – since 2005
- USPS – since 2005
- Bureau of Federal Prisons – since 2009

- **SLEP is a Fee-For-Service Program**

SLEP Candidates

- SLEP is designed (cost effective) for large stockpiles of medical materiel held in environmentally controlled locations
- Primarily FDA-approved prescription drug (not biological) products are nominated by program participants
- Current testing focuses on military significant or contingency use products
- Drugs that have limited commercial use (e.g. nerve agent antidotes)
- Drugs that are purchased in very large quantities, such as ciprofloxacin, doxycycline, Tamiflu (currently not Relenza)

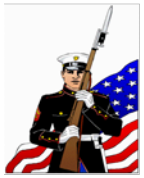
SLEP Basics

- Representative samples from one location are requested and sent to the FDA
- FDA laboratories test the samples using methods from the U.S. Pharmacopeia (USP) or FDA requests the drug manufacturer's test methodology
- FDA analytical data on the samples are evaluated by FDA to determine if the lot can be extended and for how long (includes statistical extrapolations)
- FDA-determined shelf life extensions are sent to the DMSB and this is provided to SLEP participants

SLEP Basics (cont'd.)

- The first time a lot is tested in SLEP, a 2-year shelf life extension is given (maximum)
- FDA grants extensions to a specific lot number, with an understanding that all lots at all locations have been stored under cGMP, including environmentally controlled storage conditions
- The same lot is retested annually or semi-annually to confirm extended expiration dating or permit further extension
- SLEP materiel must be relabeled in accordance with FDA regulations (including cGMP)
- Agreement of all participants that products that fail testing at any time are destroyed

SLEP Program Operation



Drug Lot Stored in Military/SNS/VA Stockpile

Samples →

SLEP Military/ SNS/VA Contact

Samples

New Expiration Date

FDA Field Lab "Testing"

Samples →

← Test Results

FDA SLEP Coordinator

Tests/Test methods/Location of standards/procedures/research (when needed)

Data Evaluation, Analysis, and Estimations of New Expiration Date

FDA CDER Chemist Analysis

SLEP & States

- May 2006 *National Strategy for Pandemic Influenza: Implementation Plan:*
  - "HHS, DoD, VA and the States shall… explore the possibility of broadening SLEP to include equivalently maintained State stockpiles, within 6 months"

- FDA-led interagency workgroup formed, included DoD, VA, and CDC
- HHS determined that the inclusion of State stockpiles of antiviral drugs in SLEP was not feasible at that time

Feasibility Issues

Programmatic Issues:

- A large increase in SLEP customers could have a negative impact on program efficiency
- Consolidation of SLEP customers to facilitate the collection of samples and funding may be desirable

Resource Issues:

- USG SLEP administrator and FDA would require significant additional funding for expansion
- States/locals need to assess program costs
- Uncertainty as to size and scope of program

Feasibility Issues (cont'd.)

Quality assurance / Quality control:

- States/locals would need to have adequate quality control programs (including facility design, maintenance, security, appropriate storage environment, labels and relabeling, recordkeeping, tracking, monitoring)
- USG would need to monitor program compliance (inspections)

Legal Issues:

- Current program is an exercise of enforcement discretion
- Concern about liability for SLEP participants
- Need to determine appropriate mechanism for agreement with States

SLEP, EUA and H1N1 Response

- Tamiflu capsules and suspension held by the SNS, much of which had been SLEP-tested, were distributed to states and locals

- FDA issued Emergency Use Authorizations (EUAs) allowing use of product beyond labeled shelf life, including product that had been SLEP-tested product

Today's SLEP Conversation is Designed to:

- Provide States/locals with detailed cost projections to assess the value of participation in a SLEP type program
- Determine States/locals interest to participate in SLEP and potential program size and scope